



Pacifier Use in Children: A Review of Recent Literature

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Abstract

Pediatric dentists are generally well aware of the oral implications of nonnutritive sucking (NNS). NNS via digit or pacifier can effect changes in the occlusion, including openbite, excessive overjet, and possibly posterior crossbite. Skeletal changes have also been attributed to NNS. There is some evidence that pacifiers may do less harm to the dentition, particularly because pacifier habits are often spontaneously shed at about 2 to 4 years of age. Digit habits are more likely to persist into the school-age years and can require appliance therapy for discontinuation. Thus, some authorities suggest that pacifiers be recommended for infants who engage in NNS.

While pediatric dentists understand the oral and perioral effects of pacifiers, they may be less well versed in other aspects of pacifier use that have been reported in the medical, nursing, chemical, and psychological literature. This paper provides reviews of literature concerning the role of pacifier NNS in 4 areas: (1) sudden infant death syndrome; (2) breast-feeding; (3) otitis media and other infections; and (4) safety. Knowledge of current literature in these areas may assist pediatric dentists with their decisions of whether to recommend or discourage pacifier use in infants. (*Pediatr Dent.* 2003;25:449-458)

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Nonnutritive sucking (NNS) with pacifiers in various forms has been used by humans for possibly thousands of years. NNS can soothe infants and young children, assist with transitioning to sleep, alleviate the discomfort of teething, and provide comfort during stressful episodes. The dental literature has focused on the changes created by pacifier NNS on the occlusion and perioral tissues.¹⁻⁶ Pediatric dentists should be aware of other risks and benefits of pacifier use, some controversial, that have been reported in the literature. These include:

1. an association with protection against sudden infant death syndrome (SIDS);
2. an association with reduced prevalence and reduced duration of breast-feeding;
3. an increased risk for otitis media and other infections.

In addition, pediatric dentists should also be aware of safety issues related to pacifier use.

Knowledge of these areas may be helpful in the risk-benefit considerations that should be considered in a decision as to whether to recommend pacifier use to the parents of infants and young children. In general, however, these are topics that usually appear in the medical, nursing, and psychological literature as well as journals of other disciplines.

The aims of this paper are to:

1. provide reviews of recent literature regarding the roles of pacifiers in the aforementioned areas (assessments of the strength of the evidence are based on the scale presented in Table 1⁷);
2. provide a broad view of pacifier use that may assist in decisions on whether to recommend or discourage pacifier use in infants;
3. present suggestions that can reduce the risks and enhance the benefits of pacifier use.

Table 1. Scale for Classifying the Strength of the Evidence from Scientific Studies⁷

Level	Criteria
I	Evidence obtained from 1 or more properly conducted randomized clinical trials (using concurrent controls, double-blind design, placebo, valid and reliable measurements, and well-controlled study protocols).
II-1	Evidence obtained from a controlled clinical trial without randomization (one using systematic subject selection, some type of concurrent controls, valid and reliable measurements, and well-controlled study protocol).
II-2	Evidence obtained from a well-designed cohort or case-control analytic study.
II-3	Evidence obtained from a cross-sectional comparison between times and places; or a study using historical controls; or dramatic results in an uncontrolled experiment.
III	Opinion of respected authority on the basis of clinical experience; or a descriptive study or case report; or a report of an expert committee.

Literature searches

Articles were selected for review if pacifier use was one of the main focuses of an experimental or observational study, or meta-analysis. The review encompasses studies published since about 1950, and published in English. Medline searches used the keywords nonnutritive, sucking, pacifiers, dummies, and oral habits. Evidence-based searches were done using the following:

1. For treatment, searches were limited to clinical trials (I, II, III, IV; controlled; randomized clinical), meta-analysis, and multicenter studies.
2. For diagnosis, searches were limited to sensitivity and specificity, likelihood functions, and mass screening.
3. For etiology/harm, searches were comprised of cohort studies, case control studies, and risk.
4. For natural history/prognosis, searches included prognosis, cohort studies, disease progression, and time factors.

The reference lists of all selected articles were scanned for additional candidates for review. In general, editorials, general reviews, and abstracts of studies were not reviewed. The review also excluded textbooks and chapters. Case reports were included in the review of pacifier safety.

The relationship between pacifier use and sudden infant death syndrome

Sudden infant death syndrome (SIDS) is defined as “the sudden death of an infant under 1 year of age which remains unexplained after a thorough case investigation, including performance of a complete autopsy, examination of the death scene, and review of the clinical history.”⁸ Several studies have focused attention on the infant’s sleeping environment as providing factors affecting the risk for

SIDS. These include sleeping position, bedding, bed sharing, and breast- or bottle-feeding.⁹⁻¹³ The peak incidence of SIDS occurs at ages 2 to 4 months.¹⁴ In recent years, the role of pacifier use in SIDS has been evaluated in several observational studies.

Mitchell et al were the first to publish data linking pacifier use with a protective effect against SIDS.¹⁵ In their case-control study, the reported usage rate of pacifiers at the last sleep of SIDS victims was about half of that reported for control infants at the sleep period chosen for comparison (“nominated” sleep). The odds ratio (OR) for pacifier use at the last or nominated sleep was 0.43 in a multivariate analysis that controlled for several confounding variables. The statistically significant OR indicated that pacifier use at sleep times was associated with a greater than 50% reduction in the risk of SIDS.

Six more studies confirmed the association between pacifier use and a reduced risk of SIDS.¹⁶⁻²¹ Not all studies found a difference between cases and controls in “usual” pacifier usage. A seventh study²² found no difference among SIDS cases and controls for pacifier use “usually” and at the “last sleep.”

The published case-control studies were meticulously designed and executed. The level of evidence for this type of study is II-2 (Table 2). Case-control studies cannot prove causality nor the mechanism(s) by which pacifiers exert their SIDS-protective effect. The authors of these studies and others in the field, however, have speculated on possible explanations that fall into several categories, specifically airway and respiratory issues, position during sleep, arousal from sleep, and miscellaneous possibilities. These hypotheses are enumerated in Table 2.

The last suggestion, that pacifier use may alter the mother’s behavior, implies that pacifier use may be a marker for some undetermined aspect of child care that is itself protective for SIDS (eg, maternal behavior and attitudes and socioeconomic status). Another question arising from these case-control data is whether the true effect might be to increase the likelihood of SIDS by not giving a pacifier to an at-risk infant who usually uses one at sleep time. One unpublished study²³ evaluated infants who had sometimes used a pacifier but not for the last (SIDS) or reference (control) sleep. They were compared to groups of infants who did use a pacifier at the last/reference sleep. Some of these infants were habitual pacifier users and some had never used a pacifier previously. The comparison indicated a significantly increased risk for death from SIDS among at-risk infants who usually used a pacifier but who did not use one at the last sleep.

Righard (1998)²⁴ suggested that the findings of a protective effect against SIDS may be a bias generated by the parents of SIDS victims in their responses to questions about their deceased infants. He suggested that parents of SIDS victims might deny giving pacifiers to their infants at the last sleep, prompted by their belief that infants should not sleep with pacifiers. Righard further suggested that most of the hypotheses mentioned above, especially those

regarding the airway, would be true only as long as the infant had the pacifier in its mouth. Weiss and Kerbl²⁵ determined in a small sample of infants that the average duration of pacifier-sucking episodes during sleep was only about 11 minutes.

Opinion is divided on whether to recommend that parents routinely offer pacifiers to their children as a SIDS deterrent. Some authors are concerned about data relating pacifier use to decreased breast-feeding and increased risk for otitis media. Other authors have suggested that pacifiers should not routinely be discouraged,¹⁶ or should be recommended "at least for bottle-fed infants."¹⁸

The effect of pacifier use on breast-feeding

A mother's decision to breast-feed her newborn infant is based on multiple factors. Recent decades have witnessed a trend toward reductions in the initiation and duration of breast-feeding, particularly in developing countries. Simopoulos and Grave²⁶ listed several factors possibly associated with decreased breast-feeding:

1. lower maternal educational level;
2. lower socioeconomic status (SES);
3. first-born children;
4. socio-cultural factors;
5. maternal employment outside the home;
6. marketing of infant formulas;
7. influence of health care personnel;
8. insufficient milk syndrome, mastitis, or abnormalities of breast or nipple.

Some have suggested that this trend is a consequence of life in industrialized nations, but others have questioned whether it is indeed irreversible.²⁷

Pacifier use as a factor negatively associated with breast-feeding received little attention until the 1990s. Early in that decade, the United Nations Children's Fund and the World Health Organization began a joint program entitled the Baby-Friendly Hospital Initiative (BFHI), a comprehensive effort to encourage health care providers to establish hospital programs to promote and support breast-feeding.²⁸ The BFHI program recognizes and re-

Table 2. Explanations Offered for the Protective Effect of Pacifier Use in Sudden Infant Death Syndrome

Category of effect	Explanation	References
Airway compromise or restriction and effects on respiration	1. Pacifier use may keep the tongue in a more forward position, reducing the possibility of airway occlusion, particularly in the supine position.	18, 95
	2. Pacifier use may increase upper airway muscle tone and reduce the likelihood of airway collapse during sleep.	18
	3. Pacifiers may reduce the number and severity of apneic periods by stimulating respiratory drive.	20
	4. Pacifier use raises the infant's carbon dioxide level slightly. This acts as a respiratory stimulant and lowers the infant arousal threshold.	18
	5. Pacifiers may ease the transition to oral breathing from nasal breathing if the nasal airway becomes occluded.	20
Sleep position	1. Pacifiers may prevent an infant from turning to a prone position. ²¹ If turned in that position, the pacifier may keep the infant's nose off the bed. ^{16,19} The prone position has been associated with a risk for SIDS.	15, 18, 20
	2. An infant with a pacifier may be more likely to keep its nose free of bedding to maintain an adequate air supply.	18
	3. Because the pacifier is associated with pleasure and satisfaction, its use will promote less movement during sleep to reduce the risk of losing the pacifier.	18
	4. A pacifier quiets a restless infant and reduces the likelihood that the infant will place its head under the bedcovers.	18
Infant arousal during sleep	1. Pacifiers may decrease the arousal threshold for infants.	32
	2. Frequent loss of the pacifier during sleep may cause arousal.	96
Miscellaneous suggestions	1. Pacifiers may reduce the potential for gastroesophageal reflux.	98
	2. Pacifiers may stimulate saliva production, which, in turn, may provide protection against SIDS through unknown means.	96
	3. The production of saliva stimulates swallowing, which may play some protective role.	96
	4. Pacifiers may stimulate the release of somatostatin and gastrin, which may have some protective effect.	96
	5. Pacifier use by the infant may alter its mother's behavior, causing her to check her infant more frequently for pacifier loss.	96

Table 3. Breast-feeding/Pacifier Data From SIDS Studies

Mitchell et al ¹⁵ : Control infants who used a pacifier were less likely to engage in exclusive breast-feeding upon discharge from the obstetric hospital ($P<.001$). This was also true of the controls who used a pacifier at the nominated sleep ($P<.001$).
L'Hoir et al ²⁰ : "Dummy use and the initial choice for breast- or bottle-feeding were not correlated."
Fleming et al ²¹ : "...there was a clear association between pacifier use and lower prevalence, as well as shorter duration of breast-feeding. . ."
Franco et al ³² : "Compared with nonusers, pacifier users were more frequently bottle-fed than breast-fed ($P=.036$)."

wards health care facilities that adopt its recommendations and encourage breast-feeding. Step 9 of the program states: "Give no artificial teats or pacifiers (also called dummies or soothers) to breast-feeding infants." However, Schubiger et al,²⁹ evaluated the effect on breast-feeding of hospital adherence to this policy in Switzerland. They determined that bottle-feeding with or without pacifier use did not influence the duration of breast-feeding during the infants' first 6 months of life.

In the last decade of the 20th century, a number of studies evaluated the impact of pacifier use and other factors on breast-feeding initiation and duration. Several studies have reported statistically significant ORs or relative risks (RRs) for early weaning/decreased duration of breast-feeding in pacifier users compared to nonusers.^{30,31} In addition, several of the studies evaluating pacifier use and SIDS included breast-feeding duration differences as a variable among pacifier users and nonusers (Table 3).

Aarts et al,³³ found that breast-feeding duration and prevalence in a Swedish population were adversely related to NNS via pacifiers, but not thumbs. They also noted that occasional pacifier use was not associated with a decrease in breast-feeding duration. This same group³⁴ found similar results for pacifiers in another study, although the statistical tests did not control for confounding variables. Riva et al³⁵ found a relationship between decreased prevalence of breast-feeding and pacifier use among Italian infants. Other factors negatively associated with breast-feeding included mothers who worked, higher SES, maternal smoking, and longer stay in the maternity hospital. Marques et al³⁶ found that the primary factors associated with the introduction of other milk in the diet of Brazilian infants within the first month were:

1. pacifier use in the first week;
2. intention to start other milk in the first month;
3. giving water or tea in the first week;
4. leaving the maternity ward prior to beginning breast-feeding.

Other studies have also blamed pacifier use for shorter duration or lower prevalence of breast-feeding.^{37,38}

The explanations for the relationship between pacifiers and breast-feeding have been largely a matter of conjecture. An early suggestion for the pacifier/breast-feeding connection is that of "nipple confusion," or "sucking confusion."³⁹ This hypothesis suggests that early use of a pacifier and/or bottle will cause some infants to adopt a faulty breast-feeding technique that leads to early weaning. Some infants in one study⁴⁰ had adopted an incorrect sucking technique immediately after birth, indicating that this type of sucking is not necessarily precipitated by pacifier use. The nipple confusion hypothesis was refuted by Howard et al,³⁰ who found no relationship between pacifier use and short-term (3 months) breast-feeding. Righard and Alade⁴⁰ also found that early introduction of pacifiers was not associated with breast-feeding problems, although pacifier users had a reduced breast-feeding duration.

The decision to discontinue breast-feeding may be as complex as the decision to begin breast-feeding. Vogel et al⁴¹ studied the breast-feeding plans of mothers before or at the birth of their infants. Some planned for a brief duration, while others were undecided. In addition, 9% of the mothers stated that their breast-feeding plan was determined at least in part by the father.

The cohort design used in the majority of these breast-feeding studies gives them a level of evidence of II-2 (Table 2). Cohort studies allow only the determination of associations between pacifier use and breast-feeding initiation or duration; causality cannot be demonstrated. It is possible that pacifier use may be associated with another aspect of infant care that prompts a mother to wean her infant from the breast at a younger age. Victora et al⁴² employed an ethnographic analysis to demonstrate that mothers in a Brazilian population had a positive view of pacifier use. A substantial number of the mothers admitted to using pacifiers to control the interval between breast-feedings, or to wean their infants from the breast. The authors concluded that pacifiers may be an effective means for weaning, especially among those who experience breast-feeding problems. Newman³⁹ suggested that a number of breastfeeding problems occur because of the early use of pacifiers and bottle-feedings' incorrect sucking technique, nipple confusion, (mother's perception of) insufficient milk, mastitis, sore nipples, "breast milk jaundice," and infant refusal to take the breast.

However, it is reasonable to consider that mothers who do not plan to breast-feed, who plan to breast-feed for a short period, or who are undecided, may use a pacifier (as opposed to the breast) to comfort the infant and assist in weaning. This conclusion was alluded to by Clements et al⁴³ in their study of English women. The authors speculated that early use of pacifiers may reflect a parental choice to bottle-feed.

Other data exist to refute the early weaning hypothesis. Gale and Martyn⁴⁴ retrospectively studied individuals who had been raised in Hertfordshire, England between 1911 and 1930. Data collected by visiting health workers during that time indicated that pacifier users were less likely than nonusers to be weaned from breast-feeding by the age of 1. Kramer et al⁴⁵ published the only randomized controlled trial (level I) to date that studied causality in the pacifier-breastfeeding controversy. In the experimental group, mothers were asked to avoid pacifiers by comforting fussy infants with the breast or by carrying and rocking. In the control group, pacifiers were discussed as an option. The authors analyzed their data in 2 ways—first as a randomized trial, secondly ignoring randomization. In the randomized analysis, a higher percentage of parents in the experimental group practiced total pacifier avoidance (39% vs 16%). Daily use and mean number of daily pacifier insertions were also lower in the experimental group. The analysis of the randomized trial showed no significant difference between the experimental and control groups on

Table 4. Hypotheses for the Relationship Between Pacifier Use and Acute Otitis Media (AOM)

Category of effect	Explanation	References
Alteration of nasopharyngeal function	1. Elevation of the soft palate blocks the nasopharynx and impairs eustachian tube function. However, digit sucking, which should have a similar effect, has not been associated with an increased risk for acute otitis media (AOM).	47
	2. Pacifier use may alter the dental occlusion and the growth pattern of the nasopharynx, leading to functional impairment. However, this same study did not find a relationship between pacifier use and respiratory symptoms other than AOM.	97
	3. Pacifiers allow the transudation of fluid into the middle ear, assisted by pressure changes during sucking.	99
	4. Pacifiers assist with the transfer of microorganisms from the nasopharynx into the middle ear.	48
Pacifier as a vector of infection	1. Pacifiers could act a vector for the spread of viruses. This might be particularly true in day care centers.	48
	2. Pacifiers may promote the growth of pathogenic bacteria in the nasopharynx. However, Brook and Gober were unable to culture AOM-associated bacteria from pacifiers used by children diagnosed with AOM.	48, 57
Reduced antibody protection	1. Pacifier use is associated with a decreased duration of breast-feeding, which in turn may reduce maternal antibody protection against AOM. However, Niemelä et al ⁴¹ did not find a relationship between breast-feeding duration and AOM.	47
Miscellaneous	1. The reduction in breast-feeding may lead to increased intake of cow's milk, which could in some way promote AOM.	52
	2. Pacifiers are used to comfort chronically ill infants, including those with recurrent bouts of AOM.	55
	3. Pacifier use is a marker for some other variable(s) that are a risk factor for AOM.	96

weaning at 3 months. When randomization was ignored, however, a strong association was found between exposure to daily pacifier use and weaning by 3 months. These findings strongly suggest that pacifier use is a marker, but not a cause, of breast-feeding difficulties or reduced breast-feeding motivation.

The relationship between pacifier use, acute otitis media, and other aspects of health

Acute otitis media

Otitis media is a viral or bacterial infection of the middle ear. It usually occurs secondary to an upper respiratory tract infection. While it may occur at any age, its occurrence peaks at ages 3 to 36 months and 4 to 6 years. The etiologic agents may migrate from the nasopharynx to the middle ear via the eustachian tube by moving over the surface mucosa, or by propagating in the lamina dura as a thrombophlebitis or cellulitis. Clinical signs and symptoms include pain, possible hearing loss, fever, nausea, vomiting, and diarrhea. The diagnosis is usually made clinically by vi-

sualizing an erythematous tympanic membrane and otorrhea. The condition generally resolves with antibiotic treatment, although myringotomy may be necessary.⁴⁶

References to the relationship between pacifier use and acute otitis media (AOM) were made early in the 20th century. Research on this association began in the last quarter of the 20th century with a relatively small number of cohort studies. Statistically significant but relatively modest relationships between AOM and pacifier use were demonstrated.⁴⁷⁻⁵¹

One meta-analytic study⁵² evaluated several risk factors for AOM. Only 2 studies^{47,53} met the criteria for inclusion in the analysis. The pooled estimate of the RRs was 1.24 (CI=1.06-1.46). The meta-analysis pooled the individual crude risk ratios for each factor, an approach that does not consider the roles of confounding variables.

Larsson⁵³ reported significantly higher percentages of children with a history of

AOM among those who had used a pacifier for ≤ 4 years compared to children with digit habits or no NNS habit. Jackson and Mourino⁵⁰ found a higher prevalence of AOM history among pacifier users compared to nonusers. However, bottle-feeding and day care utilization posed higher risks than did pacifiers. Niemelä et al⁴⁷ found an increased risk for AOM among Finnish pacifier users. They used retrospective questionnaires to assess the incidence of AOM, a method that may underestimate its true incidence. In another cohort study, Niemelä et al⁴⁸ determined that pacifier use was associated with recurrent AOM in Finnish children under the age of 4 years who attended day care centers. The cleanliness of pacifiers in that setting was not assessed. In a third study,⁴⁹ they studied pairs of well-baby clinics in Finland. One clinic in each pair instructed parents to discontinue pacifier use after their infants had reached 6 months of age. Parents were also requested to record occurrences of AOM. Reductions in the use of pacifiers resulted in fewer episodes of AOM. Pacifier use may have been underreported by parents from the intervention clinics. Criticism of other aspects of the study design have been made.⁵⁴ Warren et al⁵¹ found several factors that were

associated with AOM during the first year of life: (1) higher family income; (2) higher maternal and paternal education; (3) race (white); and (4) day care attendance. Pacifier use was significantly related to reported episodes of AOM at 9 months, but not at 12 months. The OR for pacifier use, 1.20 (CI=1.03-1.39), was modest.

The hypotheses for the relationship between pacifier use and AOM are listed in Table 4. The majority of these studies used the cohort design (level II-2; Table 2). These studies can assess relative risks in a sample, but they cannot determine causality. Multiple risk factors for AOM have been identified (parental smoking, bottle-feeding, mouth breathing, use of day care, socioeconomic variables, etc). The true association may be a relationship between pacifier use and 1 or more of those factors. As stated by North et al,⁵⁵ "One question that arises. . . is that of whether the use of the pacifier leads to an increased risk of ill health or whether it is fact that children with more health problems are more likely to be given a pacifier to soothe and comfort."

Pacifiers as vectors for bacterial and fungal transport

An issue raised by the AOM studies is whether and to what extent pacifiers are fomites for infection. Barton⁵⁶ swabbed the surfaces of pacifiers and thumbs then placed the swabs in an unspecified growth medium. Based on the culture results, he stated that the thumb was more than 10 times as septic as the pacifier, and that "the use of the dummy is far less baneful than to allow the child to suck its thumb."

Six more recent studies offer conflicting evidence.⁵⁷⁻⁶² Several suggested an association between pacifier use and bacteria or yeast (chiefly *Candida albicans*) infections. Other support for *C. albicans* transport comes from a case report.⁶³ One case-control study⁶⁴ found that pacifier sharing was a risk factor (OR=2.1) for meningococcal disease. However, that study combined pacifier sharing with sharing items of food or drink.

One in vitro study⁵⁷ suggested that only some pacifiers carry microorganisms and that they do so only in small numbers. The authors did not believe that pacifier-associated infections could be explained by microbial colonization of the pacifier. Sio et al⁵⁹ found a lower association with oral infections from silicone vs latex pacifiers. Darwazeh and Al-Bashir⁶⁰ found no difference in the prevalence of positive oral candidal cultures between bottle-fed and breast-fed infants. It is reasonable to assume that the bottle-fed infants in that study were using reusable latex nipples, though they may have been cleaned between feedings.

Ollila et al⁶¹ suggested that pacifier use may:

1. reduce oral sugar clearance;
2. increase the number of receptor sites for microbial adhesion; or
3. interfere with the mucosa in a way that favors candidal colonization.

Hannula et al⁶² found several other factors associated with the presence of oral yeasts in infants:

1. eruption of the first primary tooth at age >6 months;
2. mother cooling the infant's food by blowing on it;
3. mother cleaning the pacifier by licking it.

Issues related to safety of pacifiers and pacifier components

Pacifier safety issues sort themselves into 3 principal areas: (1) physical; (2) chemical; and (3) immunological.

Physical safety

Pacifier materials and design, combined with improper usage, have contributed to reported morbidity and mortality associated with mishaps. The following are representative of reports regarding these incidents.

Asphyxia has been reported several times over the past 30 years.⁶⁵⁻⁷⁴ Kravath⁶⁹ described the asphyxiation of a 5-month-old who was using a pacifier that had a stylized mouse's head in place of the usual ring. Attempts to dislodge the pacifier from the pharynx by pulling on the mouse's head resulted in the nipple portion pulling through the flange. The flange remained in the pharynx, resulting in death. Simkiss et al⁷³ described a more fortunate outcome in a 6-month-old infant who began choking on her pacifier. The infant's parents were unable to remove it. A tracheostomy was performed in the emergency room, and the pacifier was eventually removed. The authors of both cases remarked on the force that was required to dislodge the pacifiers once the flanges were positioned behind the soft palate. Jones⁷⁵ reported on an 8-month-old who had swallowed a flanged pacifier with resultant respiratory distress, but the outcome was not fatal. Two cases^{68,71} involved makeshift pacifiers, while a third⁷² involved a candy pacifier. Scherz⁷⁶ suggested that "preemie nipples" are also a potential hazard.

Simkiss et al⁷³ and Williams⁷⁴ stated that ventilation holes in pacifier flanges are essential. They also recommended that flanges have minimum horizontal and vertical dimensions of 43 mm, and that manufacturers be required to place a ring behind the flange.

A survey on strangulation⁷⁷ reported cases in which a cord attached to the pacifier caught on a part of the infant's crib. The authors noted that the United States Consumer Product Safety Commission (USCPSC) does not allow pacifiers to be sold with cords attached. Further, the USCPSC requires manufacturers to provide a warning with pacifier packaging that warns parents/caregivers not to attach cords. The issue of the "grasp ring" is still a dilemma. Some suggest that they be banned because they invite cord attachment. Others recommend that they be required to facilitate removal in case of aspiration.

Larsson⁷⁸ reported that about one third of pacifier users in one study placed the lower edge of the flange between the lower lip and the lower incisors. This may cause damage to the dentition and the periodontal support for those teeth.⁷⁹ A case of gingival damage was reported⁸⁰ in an infant who positioned the pacifier shield as described by Larsson.

Izenberg et al⁸¹ reported on an 18-month-old who fell from her stroller with a pacifier in her mouth. She suffered a laceration along the lower border of both alar cartilages. The lacerations were contiguous beneath the columella, lifting the soft tissues covering the tip of the nose. The cause of this "cookie cutter" laceration was determined by noting that

the shape of the upper edge of the flange corresponded precisely to that of the laceration.

Stubbs and Aburn⁸¹ reported on a 14-month-old male who suffered a horizontal laceration below his right eye caused by his pacifier. The injury included a laceration of the conjunctiva and sclera, which led to extrusion of vitreous, discoloration of the iris, and sluggish reaction to light. Normal color and function returned after 1 week of treatment.

Fencia et al⁸³ reported a case of infant botulism in a 9-week-old female whose pacifier had been sweetened with honey contaminated with *Clostridium botulinum* spores. The authors recommended that honey be avoided as a sweetening agent in infants under the age of 1 year. A report by Pedra et al⁸⁴ described 5 cases of large traumatic ulcers of 2 weeks to 4 months duration on the palates of infants. The authors determined the cause of the ulcers to be trauma from the use of standard bottle nipples in all 5 cases and pacifiers in 4 of the cases. The ulcers resolved after nipple orifices were enlarged and feeding position was corrected in 3, pacifier use was discontinued in 1, and bottle and pacifier use was discontinued in another.

Pacifier safety standards were promulgated by the USCPSC in October 1976. These standards require that pacifiers be designed and constructed in a manner that would protect the user under reasonably foreseeable conditions of use from pharyngeal obstruction, strangulation, wounding, ingestion, or aspiration of the pacifier or any of its components. The regulations specify the size of the flange, the strength of the components, and means for testing to meet these standards. The USCPSC also forbids the sale of pacifiers with a cord, ribbon, chain, or similar device attached, and it requires package warnings to caregivers to "never tie pacifiers or other items around your child's neck."

Chemical safety: N-nitrosamines in pacifiers

During the processing of natural rubber and the creation of synthetic rubber products, a variety of substances are added, including accelerators, antioxidants, reinforcing agents, N-nitroso compounds, and various amines and alkyl carbamates. N-nitrosamines and N-nitramines form when stabilizers and accelerators derived from dialkylamines contact the nitrosating agents. Despite repeated extractions of N-nitrosamines and their precursors, these compounds may persist for the lifetime of a manufactured rubber article.

Volatile N-nitrosamines have been shown in animal tests to be potent carcinogens. Studies^{85,86} have reported the presence of N-nitrosamines in baby bottle nipples and other rubber products, and have determined that these compounds can be extracted via an aqueous simulated saliva, suggesting that they could be ingested by an infant during feedings or NNS. Further, infants may also ingest N-nitrosamine precursors that may be nitrosated in the stomach when combined with nitrite from the saliva.

Concern over these compounds has prompted most industrialized countries to adopt regulations regarding baby bottle nipples and pacifiers.^{87,88} In the United States, the

regulations specify that no component of the pacifier may contain more than 20 parts per billion of total volatile N-nitrosamines as determined by dichloromethane extraction. Pacifiers may not have sharp points or edges painted with paint that contain more than 0.06% lead.

Immunologic safety: latex allergy

Mäkinen-Kiljunen et al⁸⁹ reported on 3 infants with allergies related to pacifier use. The conditions of all 3 improved when pacifier use was discontinued. Venuta et al⁹⁰ reported a case of a child who used a pacifier and who developed a cough resistant to conventional treatment. Suspecting that the cough might have an allergic basis, the latex pacifier was replaced by a silicone product. The cough abated, confirming the authors' suspicions about latex allergy.

Niggemann et al⁹¹ investigated the associations between early sensitization to latex and various lifestyle factors, including pacifier use. They enrolled almost 400 children from a prospective birth cohort study. By age 5 years, 20 (5%) demonstrated specific serum IgE to latex. Sensitization was evident after age 1, and 19 of the 20 sensitized children demonstrated increasing specific IgE levels over time. All 20 were atopic. The latex-allergic children had undergone significantly more operations ($P < .05$) than the nonallergic group. However, no differences were found between the latex-allergic and nonallergic children in exposure to pacifiers. The authors concluded that no risk factors for developing latex allergy could be identified in pacifier-using children up to 5 years other than atopic predisposition and the number of surgical procedures.

The USCPSC regulations do not address latex allergy, and no latex allergy warning is currently required on pacifier labels. Some silicone pacifiers, however, are labeled "nonlatex" as a safety statement and, probably, a marketing tool. Parents and caregivers of children with latex allergies are quite aware of consumer products that contain latex and would likely be drawn to silicone products for their children.

Recommendations

A few common sense steps can be taken to enhance the benefits and reduce the risks of pacifier use:

1. Educate parents and caregivers about the safe use of pacifiers.
2. Withhold the use of pacifiers until breast-feeding is established. After that point, limit their use for soothing breast-fed infants.
3. Advise parents and caregivers to exercise judgment and restraint regarding pacifier use. They should be taught to avoid ad lib use throughout the day.
4. Instruct parents and caregivers to clean pacifiers routinely and avoid sharing between siblings. Parents should not lick pacifiers to clean them. Parents should consider having several pacifiers to rotate through cycles of cleaning and use during the day.
5. Suggest to parents that pacifier use be curtailed beginning at 2 years of age and that pacifier habits be

discontinued by or before age 4 to minimize the development of malocclusion.

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